Baxter Healthcare Corporation
34175 Ardenwood Blvd.
Fremont, California 94555
510.818.4600

SEP - 5 2003

K031882

Baxter
BioScience

510(k) SUMMARY

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92.

A. Name, Address, Phone and Fax Number of the Applicant

Baxter Healthcare Corporation
34175 Ardenwood Blvd.
Fremont, CA 94536

Telephone: (510) 818-4600
Fax: (510) 818-4700

B. Contact Person

Lori DonDiego
Senior Manager, Regulatory Affairs

C. Date Prepared

June 16, 2003

D. Device Name

Trade Name: Endoscopic Applicator
Common Name: Endoscopic Applicator
Classification Name: Endoscopes and Accessories

E. Device Description

The Endoscopic Applicator is a re-usable applicator used to deliver hemostatic agents to bleeding surgical sites. The Endoscopic Applicator consists of two components; (1) a non-reflective stainless steel cannula, and (2) a stainless steel stylet (obturator). The Endoscopic Applicator is to be thoroughly cleaned and sterilized before each use, and can be used up to 20 times.

F. Intended Use

This Endoscopic Applicator is intended for use in delivering hemostatic agents to bleeding surgical sites through a 5mm or larger trocar.

G. Substantial Equivalence

The Endoscopic Applicator is substantially equivalent to the following commercially available laparoscopic instruments:

MedChem Surgical Endoscopic Accessory/ Delivery System	MedChem Products, Inc.	K913172
MedChem Surgical Delivery System	MedChem Products, Inc.	K932466
Davol Surgical Mesh Delivery System	Davol, Inc.	K930147

The Endoscopic Applicator and the predicate devices have similar intended uses. They are all intended to deliver surgical products into the body. The Endoscopic Applicator is substantially equivalent to the predicate devices in intended use, design and components, materials, and performance characteristics. See Table 1.

Table 1. Comparison Table

FEATURE	NEW DEVICE	PREDICATE DEVICES		
	Endoscopic Applicator	**MedChem Surgical Endoscopic Accessory/ Delivery System K913172**	**MedChem Surgical Delivery System K932466**	**Davol Surgical Mesh Delivery System K930147**
Intended Use	This Endoscopic Applicator is intended for use in delivering hemostatic agents to bleeding surgical sites through a 5mm or larger trocar.	The MedChem Endoscopic Delivery System is used in endoscopic surgical procedures to maintain the already established pneumoperitoneum while providing a means of facilitating delivery of adjunctive surgical products (ligatures, sutures, etc.) through a trocar.	A syringe device used to facilitate the delivery of adjunctive surgical products during various surgical procedures.	Intended to facilitate the delivery of surgical mesh to the surgical site during laparoscopic soft tissue repair procedures (e.g. hernia repair).
Anatomical Sites	Endoscopic / Laparoscopic	Endoscopic	Various	Laparoscopic (abdominal soft tissue)
Sheath Outer Diameter	5mm	0.394"	0.197" - 0.750" (various)	9.7mm
Sheath Length	292mm	13.31"	8" - 13" (various)	8"
Size cannula used with	5 mm or larger	Minimum 10 mm OD	Various, depending on size of delivery system.	10 mm or larger
Main Components	Cannula Stylet	Sheath Plunger Plunger O-Ring	Sheath Plunger Plunger O-Ring	Introducer Sheath/Handle Introducer Rod/Handle

FEATURE	NEW DEVICE	PREDICATE DEVICES		
	Endoscopic Applicator	**MedChem Surgical Endoscopic Accessory/ Delivery System K913172**	**MedChem Surgical Delivery System K932466**	**Davol Surgical Mesh Delivery System K930147**
Main Materials	Stainless Steel Stainless Steel ME-92Coating	Polycarbonate Polycarbonate Silicone, Medical Grade	Polycarbonate Polycarbonate Silicone, Medical Grade	Stainless Steel/PVC Stainless Steel/PVC
Sterilization Method	Non-sterile. (Intended to be cleaned and sterilized by the user prior to the first use and then after each subsequent use.)	Gamma or dry heat cycle, SAL 10^{-6}	Gamma or dry heat cycle, SAL 10^{-6}	EtO, SAL 10^{-6}
Expiration Date (years)	N/A – reusable up to 20 times	Unknown	Unknown	Unknown
Single Use Only	Reusable	Single Use	Single Use	Single Use
Packaging	Packaging does not provide a sterile barrier. Polyethylene terephthalate-glycol (PETG) tube, Low Density Polyethylene (LDPE) poly tubing, Vinyl End Cap, 200 lb. test #3 white cardboard box.	Polycarbonate plastic tray sealed with a polyethylene lid	Polycarbonate plastic tray sealed with a polyethylene lid.	Tyvek pouch in a plastic blister tray

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 5 2003

Ms. Lori DonDiego
Senior Manager, Regulatory Affairs
Baxter Healthcare Corporation
34175 Ardenwood Boulevard
Fremont California 94555

Re: K031882
Trade/Device Name: Endoscopic Applicator
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GJC
Dated: June 16, 2003
Received: June 18, 2003

Dear Ms. DonDiego:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K 031882

Device Name: Endoscopic Applicator

Indications For Use: This Endoscopic Applicator is intended for use in delivering hemostatic agents to bleeding surgical sites through a 5mm or larger trocar.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR (Per 21 CFR 801.109) Over-The-Counter Use_____

(Optional Format 1-2-96)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K 031882